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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 685

Adopted 1 December 2015

**Requirements for Food Supplements**

*Issued pursuant to*

*Section 4, Paragraph two and Paragraph 10.1, Clause 2, Section 13, Paragraph three, Clause 3 of the Law on the Supervision of the Handling of Food and Section 7, Paragraph two of the Advertising Law*

**I. General Provisions**

1. This Regulation prescribes:

1.1. the mandatory safety requirements for food supplements;

1.2. the procedures for registering food supplements, suspending or restricting their circulation and cancelling registration;

1.3. the requirements for additional labelling of food supplements;

1.4. the requirements for the advertising content and presentation.

2. This Regulation shall not apply to medicinal products.

3. It shall be permitted to place food supplements on the market in Latvia, if they:

3.1. have been notified to the Food and Veterinary Service (hereinafter – the Service) and included in the register of food supplements;

3.2. have been presented as food products and are delivered to the end consumer in pre-packaged form only.

4. A food establishment (hereinafter – the establishment) shall ensure that there is information on the products distributed thereby at the trading site of the relevant food supplements.

5. The Service shall not restrict or prohibit the trade in food supplements due to their composition, manufacturing specification, presentation or labelling, if they conform to the requirements of this Regulation and the laws and regulations governing the circulation of food.

**II. Mandatory Safety Requirements**

6. Food supplements are foodstuffs whose purpose is to supplement the normal diet in the form of concentrated sources of nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect, alone or in combination. Food supplements are marketed in specific doses in capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

7. Maximum amounts of vitamins and minerals present in food supplements per daily dose of consumption as recommended by the manufacturer shall be set, taking the following into account:

7.1. upper safe levels established by scientific risk assessment based on generally accepted scientific data;

7.2. varying degrees of sensitivity of different consumer groups;

7.3. intake of vitamins and minerals from other dietary sources;

7.4. recommended doses of vitamins and minerals for a consumer.

8. Only such vitamins and minerals may be used in the manufacture of food supplements and in such forms as defined in:

8.1. Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements;

8.2. Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods;

8.3. Commission Regulation (EU) No 119/2014 of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods;

8.4. Commission Regulation (EU) 2015/414 of 12 March 2015 amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6S)-5- methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements;

8.5. Commission Regulation (EU) 2017/1203 of 5 July 2017 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements;

8.6. Commission Regulation (EU) 2021/418 of 9 March 2021 amending Directive 2002/46/EC of the European Parliament and of the Council as regards nicotinamide riboside chloride and magnesium citrate malate used in the manufacture of food supplements and as regards the units of measurement used for copper.

[*17 November 2020; 24 August 2021*]

**III. Procedures for Registering, Suspending or Restricting the Circulation and Cancelling Registration**

9. In order to register a food supplement, the establishment shall submit a notification to the Service for the registration of the food supplement (hereinafter – the notification) (a sample of the notification form is available on the website of the Service). The following information shall be indicated in the notification:

9.1. regarding the food supplement:

9.1.1. the name;

9.1.2. the name, the registration number in the Commercial Register, the address, telephone number, electronic mail address of the manufacturer;

9.1.3. the form of preparation;

9.1.4. the size of the unit of pre-packaging;

9.1.5. the size of the unit of packaging;

9.1.6. the recommended daily dose;

9.2. the name, the quantity of the ingredient in the recommended daily dose and unit of measure, specifying in addition:

9.2.1. the form of vitamins and minerals;

9.2.2. the botanical name of the plant in Latvian and Latin, the part used, the form of preparation. The ratio of the plant to the extract shall be indicated in addition to the plant extract;

9.2.3. substances which have a nutritional or physiological effect (this requirement shall not apply to Sub-paragraphs 9.2.1 and 9.2.2 of this Regulation);

9.3. regarding the submitter of the notification:

9.3.1. the name of the establishment, for a natural person – also the given name and surname;

9.3.2. for a legal person – the registration number in the Commercial Register and the legal address, for a natural person – the personal identity number and the address of the declared place of residence;

9.3.3. the actual address if it differs from the legal address or the address of the declared place of residence;

9.3.4. the contact person, telephone number, electronic mail address;

9.4. regarding the food establishment:

9.4.1. the name of the establishment, for a natural person – also the given name and surname;

9.4.2. for a legal person – the registration number in the Commercial Register and the legal address, for a natural person – the personal identity number and the address of the declared place of residence;

9.4.3. the actual address if it differs from the legal address or the address of the declared place of residence;

9.4.4. the contact person, telephone number, electronic mail address;

9.5. regarding payment of the State fee – the payer of the State fee, the date of the payment and the amount paid;

9.6. regarding the method of receipt of the Service decision – to the indicated official electronic address, electronic mail address, postal address or in person;

9.7. a declaration that the information provided is true.

[*17 November 020*]

9.1 In addition to the notification referred to in Paragraph 9 of this Regulation, the establishment shall submit to the Service:

9.11. a sample of the labelling text in the Latvian language;

9.12. a sample of the labelling text in the original language, the original packaging or a photocopy thereof.

[*17 November 2020*]

10. If the notification is submitted in paper form, the establishment shall in addition submit a sample of the labelling text in Latvian to the Service using the available electronic data carriers. Such procedure shall also apply in the case referred to in Paragraphs 13 and 13.1 of this Regulation.

[*17 November2020*]

10.1 The information referred to in Paragraphs 9, 9.1, 13, and 13.1 of this Regulation may be submitted by the establishment electronically by completing a special online form on the website of the Service www.pvd.gov.lv (e-service) and for identification purposes using the shared solution for the identification of a person of the State information system integrator under supervision of the State Regional Development Agency.

[*17 November 2021 / Paragraph shall come into force on 1 January 2021. See Paragraph 2 of the amendments*]

11. The Service may request an opinion from the State Agency of Medicines:

11.1. if the information indicated in the notification shows that the food supplement is a medicinal product;

11.2. if the Service establishes that the food supplement notified or included in the register is being distributed as a medicinal product in another European Union Member State;

11.3. taking into account the information received from the competent authorities of other European Union Member States.

12. The Service may, if necessary, request any other information on the food supplement from the establishment in order to assess its conformity with the requirements of the laws and regulations governing the circulation of food.

13. If changes are made to a registered food supplement, the establishment shall submit to the Service a notification of changes to a registered food supplement (hereinafter – the notification of changes) (a sample of the notification form is available on the website of the Service). The following information shall be indicated in the notification of changes:

13.1. regarding the food supplement:

13.1.1. the name and registration number of the food supplement;

13.1.2. the changes made to the name of the food supplement, the name of the manufacturer, the address of the manufacturer, the name of the establishment, the address of the establishment, the form of preparation, the size of the unit of pre-packaging, the size of the unit of packaging, the recommended daily dose, the ingredients, the quantity of the ingredients, the unit of measurement of the ingredients or the labelling;

13.2. regarding the submitter of the notification of changes:

13.2.1. the name of the establishment, for a natural person – also the given name and surname;

13.2.2. for a legal person – the registration number in the Commercial Register and the legal address, for a natural person – the personal identity number and the address of the declared place of residence;

13.2.3. the actual address if it differs from the legal address or the address of the declared place of residence;

13.2.4. the contact person, telephone number, electronic mail address;

13.3. regarding the establishment:

13.3.1. the name of the establishment, for a natural person – also the given name and surname;

13.3.2. for a legal person – the registration number in the Commercial Register and the legal address, for a natural person – the personal identity number and the address of the declared place of residence;

13.3.3. the actual address if it differs from the legal address or the address of the declared place of residence;

13.3.4. the contact person, telephone number, electronic mail address;

13.4. an indication regarding the need to maintain the labelling previously included in the register, specifying the exact period until which the labelling previously included in the register shall be kept in the register;

13.5. regarding payment of the State fee – the payer of the State fee, the date of payment and the amount paid;

13.6. regarding the method of receipt of the Service decision – to the indicated official electronic address, electronic mail address, postal address or in person;

13.7. a declaration that the information provided is true.

[*17 November2020*]

13.1 In addition to the notification referred to in Paragraph 13 of this Regulation, the establishment shall submit to the Service:

13.11. a sample of the labelling text in the Latvian language;

13.12. a sample of the labelling text in the original language, the original packaging or a photocopy thereof.

[*17 November 2020*]

14. Prior to submitting the notification referred to in Paragraphs 9 and 13 of this Regulation, the establishment shall pay the State fee in accordance with a regulatory enactment regarding the State fee for the registration of a food supplement.

15. 15. The Service shall, within a period of one month after receipt of the documents referred to in Paragraphs 9, 9.1, 13, and 13.1 of this Regulation take the relevant decision:

15.1. to register the food supplement in the register of food supplements of the Service or to refuse registration if the product does not conform to the requirements of the laws and regulations governing the field of food circulation;

15.2. to make changes in the register of food supplements or to refuse to make changes if the product does not conform to the requirements of the laws and regulations governing the field of food circulation.

[*17 November 2020*]

16. If the Service receives new information or performs repeat check of the existing information on the basis of which it may be concluded that the registered food supplement may cause or causes threats to human health, the Service shall take a decision to restrict or temporarily suspend the trade in the food supplement or to remove it from circulation. In accordance with the laws and regulations regarding the operation of the rapid alert system in circulation of food and circulation of animal feed, the Service shall without delay inform the Member States and the European Commission about the decision taken.

17. If the food supplement included in the register causes threats to human health, the Service shall take a decision to cancel the registration of the food supplement and shall delete it from the register of food supplements.

18. If the food supplement included in the register does not cause threats to human health, however, does not conform to the requirements of the laws and regulations governing the field of food circulation, the Service may take a decision to suspend the trade in the food supplement until the elimination of non-conformities. If the non-conformities detected are not eliminated, the Service may take a decision to cancel the registration of the food supplement.

19. The Service shall create and maintain a register of food supplements. The register shall be published on the website of the Service. The following information shall be included in the register:

19.1. the name and address of the manufacturer;

19.2. the name and address of the food establishment operator (for example, importer, distributor) responsible for the food supplement and involved in the circulation of food;

19.3. the list of ingredients of the food supplement and the quantity of nutrients or other substances with nutritional or physiological effect per daily dose (also names of the used plants in Latvian and Latin);

19.4. the recommended daily dose of the food supplement;

19.5. the form of preparation of the food supplement, the size of the pre-packaging and packaging unit;

19.6. text of the labelling and other information, if such is to be attached to the food supplement, for example, sample instructions for use.

20. If the food supplement included in the register of food supplements is not placed on the market anymore, the establishment shall inform the Service thereon, and the Service shall delete the food supplement from the register of food supplements.

**IV. Requirements for Additional Labelling and Advertising**

21. Food supplements shall be labelled in accordance with the procedures laid down in the regulatory enactment regarding the requirements for packaging of pre-packaged food and Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (hereinafter – Regulation No 1169/2011). The following additional information shall be included in the labelling:

21.1. the trade name “food supplement”;

21.2. the names of the categories of nutrients or substances that characterise the food supplement or an indication of the nature of those nutrients or substances;

21.3. the dose of the food supplement recommended for daily consumption;

21.4. a warning not to exceed the stated recommended daily dose;

21.5. a statement to the effect that the food supplement should not be used as a substitute for a nutritious and balanced diet;

21.6. a warning that the food supplement should be stored out of the reach of children (young children);

21.7. in numerical form – the amount of the nutrients or substances with a nutritional or physiological effect in mass or volume units per daily dose. Vitamins and minerals shall be indicated in the specified units of measurements in accordance with the requirements of the laws and regulations referred to in Paragraph 8 of this Regulation;

21.8. the amount of vitamins and minerals in percentage from the reference value of nutrients indicated in Part A of Annex XIII to Regulation No 1169/2011. The amount of vitamins and minerals in percentage may also be given in graphical form.

[*24 August 2021*]

22. The minimum daily intake of vitamins and minerals recommended by the manufacturer shall not be less than the percentage of significant vitamins and minerals listed in the first and third indents in point 2 of Part A of Annex XIII to Regulation No 1169/2011 as a percentage of the nutrient reference value.

[*17 November 2020*]

23. The amount of nutrients indicated in the labelling or of other such substances having a nutritional or physiological effect:

23.1. shall conform to the amount of a food supplement recommended as a daily dose;

23.2. shall be the average amount on the basis of the testing results of the food supplement performed by the manufacturer.

24. The labelling, presentation and advertising of the food supplement must not include:

24.1. indication that the food supplement prevents, treats or cures diseases, or mentioning of such possibility;

24.2. any explicit or implicit indications that a balanced and varied diet cannot provide appropriate quantities of nutrients.

25. It shall be permitted to advertise only food supplements included in the register of food supplements.

26. Advertising of the food supplement shall include indications “Food supplement” and “Food supplement does not replace a nutritious and balanced diet”.

27. The indication “Food supplement does not replace a nutritious and balanced diet” shall cover not less than five per cent of the volume of the advertising. The size of letters shall be such that the indication would cover as large part of the space provided for the text as technically possible.

**V. Closing Provision**

28. Abbreviation RDD (recommended daily dose) may be used for food supplements which have been placed on the market and labelled until 13 December 2016 in order to express the reference value to the amount of vitamins and minerals in percentage from the recommended daily dose indicated in Part A of Annex XIII to Regulation No 1169/2011.

**Informative Reference to European Union Directives**

This Regulation contains legal norms arising from:

1) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements;

2) Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances.

Prime Minister Laimdota Straujuma

Minister for Agriculture Jānis Dūklavs

**Annex 1**

Cabinet Regulation No. 685

1 December 2015

**Notification for the Registration of a Food Supplement**

[17 November 2020]

**Annex 2**

Cabinet Regulation No. 685

1 December 2015

**Notification of Changes in a Registered Food Supplement**

[17 November 2020]